



Recipient Information

1. Recipient Name

SEATTLE CHILDREN'S HOSPITAL
4800 SAND POINT WAY NE
SEATTLE, WA 98105

2. Congressional District of Recipient

07

3. Payment System Identifier (ID)

1910564748A1

4. Employer Identification Number (EIN)

910564748

5. Data Universal Numbering System (DUNS)

048682157

6. Recipient's Unique Entity Identifier

SZ32VTCXM799

7. Project Director or Principal Investigator

KYM R AHRENS, MD
Associate Professor
[REDACTED]@seattlechildrens.org

8. Authorized Official

Eric Tham M.D.
[REDACTED]@seattlechildrens.org

Federal Agency Information

9. Awarding Agency Contact Information

Yvonne C. Talley
Grants Management Official
EUNICE KENNEDY SHRIVER NATIONAL
INSTITUTE OF CHILD HEALTH & HUMAN
DEVELOPMENT
[REDACTED]@mail.nih.gov

10. Program Official Contact Information

Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL
INSTITUTE OF CHILD HEALTH & HUMAN
DEVELOPMENT
[REDACTED]@nih.gov

Federal Award Information

11. Award Number

5R21HD107311-02

12. Unique Federal Award Identification Number (FAIN)

R21HD107311

13. Statutory Authority

42 USC 241 42 CFR 52

14. Federal Award Project Title

An intervention to promote healthy relationships among transgender and gender expansive youth

15. Assistance Listing Number

93.865

16. Assistance Listing Program Title

Child Health and Human Development Extramural Research

17. Award Action Type

Non-Competing Continuation (REVISED)

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/01/2023 – End Date 08/31/2025

20. Total Amount of Federal Funds Obligated by this Action

\$41,611

20 a. Direct Cost Amount

\$72,385

20 b. Indirect Cost Amount

\$-30,774

21. Authorized Carryover

22. Offset

23. Total Amount of Federal Funds Obligated this budget period

\$240,544

24. Total Approved Cost Sharing or Matching, where applicable

\$0

25. Total Federal and Non-Federal Approved this Budget Period

\$240,544

26. Project Period Start Date 09/05/2022 – End Date 08/31/2025

27. Total Amount of the Federal Award including Approved Cost

\$456,997

Sharing or Matching this Project Period

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

Notice of Award



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R21HD107311-02 REVISED

Principal Investigator(s):

KYM R AHRENS, MD

Award e-mailed to: resadmin@seattlechildrens.org

Dear Authorized Official:

The National Institutes of Health hereby revises this award to reflect an increase in the amount of \$41,611 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Seattle Children's Research Institute in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R21HD107311. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Federal Direct Costs	\$185,415
Federal F&A Costs	\$55,129
Approved Budget	\$240,544
Total Amount of Federal Funds Authorized (Federal Share)	\$240,544
TOTAL FEDERAL AWARD AMOUNT	\$240,544
 AMOUNT OF THIS ACTION (FEDERAL SHARE)	 \$41,611

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
2	\$240,544	\$240,544

Fiscal Information:

Payment System Identifier: 1910564748A1
Document Number: RHD107311A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
HD	8014702	\$240,544

NIH Administrative Data:

PCC: PDB -RP / **OC:** 41025 / **Released:** 03/27/2025

Award Processed: 03/28/2025 12:05:24 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R21HD107311-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III – STANDARD TERMS AND CONDITIONS – 5R21HD107311-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R21HD107311. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the "responsible party" must register "applicable clinical trials" on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable

conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm>.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5R21HD107311-02 REVISED

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: This grant has been restored and the termination clause rescinded effective immediately. The grant will continue under the original no cost extension.

Revised Award: This revised award adds back in FY23 funding to correct the incorrect deobligation amount.

The previous terms and conditions of award remain in effect as stated below.

Termination

This award related to Transgender issues no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated.

Transgender issues

Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Closeout

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR)) within 120 days of the end of this grant to avoid unilateral closeout.

Funds in the amount of [\$40,091] may be used to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Funds used to support the orderly closeout of the study may include and must occur within 120 days:

- Assuring all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Final data collection: Conducting any necessary final study visits or data collection procedures for enrolled participants.
- Data cleaning and review: Thoroughly reviewing and cleaning collected data for accuracy and completeness.
- Statistical analysis: Performing final statistical analyses of the study data.
- Final study report: Preparing a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Creating a cleaned and locked dataset (that is suitable for sharing, if required).
- Completing all adverse event reporting and reconciliation as per protocol.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Informing all enrolled study participants of the study's termination and what study closure means for them.
- Informing study participants of their options pertaining to receiving further intervention, continuing follow-up, as appropriate.
- Confirming final disposition of investigational product(s)
- Handling any biospecimens collected and preparing them for sharing, if required.
- Updating the study record in ClinicalTrials.gov.

The institutional official should confirm that the investigators:

- Have updated ClinicalTrials.gov with the update in study status completion
- The records management and retention plan by the institution that follows the NICHD process.
- Reconcile and ensure all study invoices and trial-related contracts or costs are paid and closed.

Appeals

NIH is taking this enforcement action in accordance with 2 C.F.R. Â§ 200.340 as implemented in NIH GPS Section 8.5.2. This letter represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official

authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.

Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance.

The previous terms and conditions of award remain in effect as stated below.

REVISION

Consortium

This revised award reflects NICHD acceptance of the new consortium with the University of Hawaii per the prior approval requested email dated October 10, 2024.

The previous terms and conditions of award remain in effect as stated below.

REVISION:

This revised award reflects NICHD acceptance of the following documentation/information and removes the restriction indicated on the previous Notice of Award:

Previously pending items

Pending items: Institutional Review Board (IRB) approval

The previous terms and conditions of award remain in effect as stated below.

Clinical Trial

Dissemination Policy

The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the **application** dated **02/16/2021** and the NIH policy on [Dissemination of NIH-Funded Clinical Trial Information](#). The policy states that the clinical trial(s) funded by this award will be registered in [ClinicalTrials.gov](#) not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in [ClinicalTrials.gov](#) not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the Signing Official (SO) signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials comply with the recipient's plan addressing compliance with the Dissemination of NIH-Funded Clinical Trial Information policy. Any clinical trial funded in whole or in part under this award has been registered in [ClinicalTrials.gov](https://clinicaltrials.gov) or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to [ClinicalTrials.gov](https://clinicaltrials.gov) or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

Low Risk

Clinical Trial Study/Studies: **369855**

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the [NICHD Policies on Clinical Research](#) site.

Human Subjects

For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice [NOT-HD-20-036](#) "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice [NOT-HD-20-035](#) "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

Subcontract

This award includes funds awarded for consortium activity with the University of Washington.

SPREADSHEET SUMMARY

AWARD NUMBER: 5R21HD107311-02 REVISED

INSTITUTION: Seattle Children's Research Institute

Budget	Year 2
TOTAL FEDERAL DC	\$185,415
TOTAL FEDERAL F&A	\$55,129

TOTAL COST	\$240,544
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Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	76%
F&A Cost Base 1	\$72,538
F&A Costs 1	\$55,129